

TUKOL COUGH AND COLD HONEY FLAVOR- dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup
Genomma Lab USA

Tukol® Cough & Cold Honey Flavor Syrup

Drug Facts

Active ingredients (in each 5 mL or 1 teaspoon)	Purpose
Dextromethorphan HBr, 10 mg	Cough Suppressant
Guaifenesin, 100 mg	Expectorant
Phenylephrine HCl, 5 mg	Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
 - nasal congestion
 - cough due to minor throat and bronchial irritation

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are taking any other oral nasal decongestant or stimulant

Do not exceed recommended dosage

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or are accompanied by fever

- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than 6 doses in any 24 hour period
- this adult strength product is not intended for use in children under 12 years of age
- measure only with dosing cup provided
- keep dosing cup with product
- TSP = teaspoon

age	dose
adults and children 12 years and over	2 teaspoons (10 mL) every 4 hours
children under 12	do not use

Other information

- **each teaspoon (5 mL) contains:** sodium 3 mg
- store at 15-30°C (59-86°F). Do not refrigerate

Inactive ingredients

anhydrous citric acid, FD&C yellow # 6, flavor, glycerin, honey, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-877-994-3666

Monday to Friday from 8 am to 6 pm, Central time.

Distributed by: Genomma Lab USA Inc., Houston, TX 77098

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

Tukol®

HONEY / MIEL

COUGH & CONGESTION TOS Y CONGESTIÓN

Dextromethorphan HBr / Guaifenesin / Phenylephrine HCl
Dextrometorfano HBr / Guaifenesina / Fenilefrina HCl

Ages/Edades
12+

SABOR A MIEL

NATURAL
HONEY
FLAVOR

Relieves/Alivia:

- COUGH / TOS
- NASAL CONGESTION / CONGESTIÓN NASAL
- CHEST CONGESTION / CONGESTIÓN DE PECHO

4 FL OZ (118 mL)

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Información del Medicamento

Ingredientes activos

(en cada 5 mL o 1 cucharadita) Propósitos
Dextrometorfano HBr, 10 mg.....Supresor de la Tos
Guaifenesina, 100 mg.....Expectorante
Fenilefrina HCl, 5 mg.....Descongestionante Nasal

Usos

- ayuda a desprender las flemas (mucosidad) y a adelgazar las secreciones bronquiales para drenar las vías respiratorias.
- alivia temporalmente los siguientes síntomas que se presentan con el resfriado:
 - congestión nasal
 - tos debida a irritación menor de garganta y bronquios

Advertencias

No utilizarlo si usted está tomando un inhibidor de la monoamino oxidasa (IMAO) de prescripción (ciertos medicamentos para la depresión, condiciones psiquiátricas o emocionales, o enfermedad de Parkinson), o durante 2 semanas después de suspender el medicamento IMAO. Si usted desconoce si su medicamento de prescripción contiene un IMAO, consulte a su médico o farmacéutico antes de tomar este producto.

Consulte a su médico si usted padece

- enfermedad cardíaca ■ hipertensión
- enfermedad de la tiroides ■ diabetes
- dificultad al orinar debido a dilatación de la glándula prostática
- tos que se presenta con exceso de flema (mucosidad)
- tos persistente o crónica tal como ocurre con el tabaquismo, asma, bronquitis crónica o enfisema

Información del Medicamento (continuación)

Consulte a su médico o farmacéutico antes de utilizarlo si usted está tomando cualquier otro descongestionante o estimulante nasal oral.

No exceder la dosis recomendada.

Suspenda su uso y consulte a su médico si

- se siente nervioso, mareado o con insomnio
- los síntomas no mejoran en los siguientes 7 días o se acompañan de fiebre
- la tos persiste por más de 7 días, regresa, o se presenta acompañada por fiebre, erupción o dolor de cabeza persistente. Estos podrían ser signos de una condición grave.

En caso de embarazo o lactancia, consulte a un profesional médico antes de su uso.

Manténgase fuera del alcance de los niños. En caso de sobredosis, obtenga ayuda médica o contacte al Centro de Control de Envenenamiento de manera inmediata.

Indicaciones

- no tomar más de 6 dosis en un período de 24 horas
- este producto de concentración para adultos no está previsto para su uso en niños menores de 12 años de edad
- medir solo con la copa dosificadora incluida
- mantenga la copa dosificadora con este producto
- TSP = cucharadita

edad	dosis
adultos y niños 12 años de edad y mayores	2 cucharaditas (10 mL) cada 4 horas
niños menores de 12 años	no utilizar

Información adicional

- cada cucharadita (5 mL) contiene: sodio 3 mg
- almacenar entre 15-30 °C (59-86 °F). No refrigerar.

Ingredientes inactivos

ácido cítrico anhidro, FD&C amarillo #6, sabor, glicerina, miel, propilenglicol, agua purificada, benzoato de sodio, solución de sorbitol, sucralosa, goma xantana.

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dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-534
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (DXTROMETHORPHAN - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	2 mg in 1 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	20 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3COOX)	
HONEY (UNII: Y9H1V576FH)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	YELLOW (Amber to yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-534-04	1 in 1 CARTON	09/20/2019	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/20/2019	

Labeler - Genomma Lab USA (832323534)

Registrant - Genomma Lab USA (832323534)